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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|----------------|-------------|----------------------|--------------------|-----------------|
| 09 020,716     | 02 09 1998  | RUDOLF JUNG          | 0815               | 3572            |

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[REDACTED] EXAMINER

MCELWAIN, ELIZABETH F

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1638

DATE MAILED: 03 11 2003

EJ

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/020,716             | JUNG ET AL.         |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Elizabeth F. McElwain  | 1638                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 June 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 76-79,90-93,95-99,103,105-108,110 and 111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 76-79,90-93,95-99,103,105-108,110 and 111 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638, Examiner Elizabeth McElwain.

5           The request for a CPA filed June 10, 2002 was improper, so the application will continue prosecution as an RCE. See MPEP 706.07h, part IV. Therefore, the finality of last office action has been withdrawn. The following nonfinal office action is set forth.

The amendment filed June 10, 2002 has been entered.

Claims 76, 77, 95-97, 105-108 and 110 are newly amended.

10          Claims 100-102 and 104 have been cancelled.

Claims 76-79, 90-93, 95-99, 103 and 105-111 are pending and are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15          Claims 76-79, 90-93, 95-99, 103, 105-108, 110 and 111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20          Claims 95, 97, 106, 107 and 110, and claims 76-79, 90-93, 96, 98, 99, 103 and 105, 108 and 110-111 dependent thereon are indefinite in the recitation of "plant seed protein", since it is unclear what the metes and bounds of this term would be. Is this term intended to

mean any protein that is or can be produced in a plant seed, or proteins that are only produced in plant seeds, for example? The specification fails to further define or clarify the use of this term.

Claim 78 is indefinite because there is no antecedent basis for "plant-derived  
5 polynucleotide" in claim 95 on which it depends.

Claims 90-93 are indefinite in that they depend on cancelled claim 104.

The rejection of claims 76, 77, 98 and 99 for the recitation of "the transformed cereal plant seed is from", is withdrawn in view of the amendment of the claims.

10 The rejection of claims 78, 95-97, 104-108 and 110 for use of the phrase "plant derived polynucleotide" is withdrawn in view of the amendment of the claims.

The rejection of claims 101 and 102 for use of the phrase "about 10 times" is withdrawn in view of the cancellation of the claims.

15 The rejection of claim 104 under 35 U.S.C. 112, first paragraph is withdrawn in view of the cancellation of the claim.

Claims 76-79, 90-93, 95-99, 103 and 105-111 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is

maintained for the reasons of record set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Claims 76-79, 90-93, 95-99, 103 and 105-111 remain rejected under 35 U.S.C. 112,  
5 first paragraph, because the specification is enabling only for claims limited to transformed cereal plant seed having an elevated lysine, methionine and cysteine content (about 10% to about 35% by weight compared to untransformed cereal plant seed) comprising the modified hordothionin gene of SEQ ID NO: 2 (HT12), vectors, plant cells and transformed plants comprising said modified hordothionin gene. The specification does not enable any person  
10 skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

15 Claims 76-79, 90-93, 95-99, 103 and 105-111 remain rejected under 35 U.S.C. 102(e) as being obvious over Falco et al (U.S. Patent 5,773,691). This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

20 Claims 76-79, 90-93, 95-99, 103 and 105-111 remain rejected under 35 U.S.C. 103(a) as being obvious over Rao et al (U.S. Patent 5,885,802) in view of Applicants' Admission.

This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Claims 76-79, 90-93, 95-99, 103 and 105-111 remain rejected under 35 U.S.C. 103(a)

5 as being obvious over Rao et al (U.S. Patent 5,990,389) in view of Applicants' Admission.

This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Applicants' arguments filed June 10, 2002 have been fully considered but they are not

10 persuasive. Applicants assert that the rejection is improper given the unexpected results provided in the application and in view of the 1.132 Declaration filed subsequently.

Applicants assert that the results demonstrate that not all promoters are functional equivalents, given that the endosperm-preferred promoter, gamma-zein, produced a greater increase in lysine and methionine than the embryo-preferred promoter, Gib1. Applicants conclude that it 15 would not be an obvious modification to substitute one promoter for another. Applicants further state that there is no indication in the prior art to choose an endosperm-preferred promoter and that Falco teaches away from such a choice, asserting that "obvious to try" is not a test for patentability.

The Examiner maintains that the rejections are proper. However, it is unclear which 20 rejection applicant is arguing, given that there are two Rao et al patents that the claims are rejected under and applicant did not specify which rejection was being argued. In addition,

applicants have not specified where in the specification or in a 1.132 Declaration that support is found for the assertions regarding endosperm-preferred promoters. However, the Declaration of Jung does not provide the asserted comparison, and Table 1 at page 40 of the specification does not clearly support applicants assertions either. In Table 1, no statistical analysis is provided, the data is based on only one representative sample from one transformation event. In addition, the date in Table 1 shows that the glb1 (embryo-preferred) promoter construct resulted in higher levels of the sulfur containing amino acid, cysteine, than the gamma zein and waxy (endosperm-preferred) promoter construct. It is noted that arginine is not a sulfur containing amino acid. Therefore, the data in Table 1 does not support applicants assertions. Additionally, in view of the broad scope of the claims which encompass any endosperm-preferred promoter and any plant seed protein transformed into any cereal plant, it is submitted that the invention is still obvious in view of the prior art references. The scope of the claimed invention should be limited to the teachings of unexpected results. Furthermore, Falco is not part of the rejection, and applicants have not pointed to any part of that reference that teaches away from choosing an endosperm-preferred promoter.

Claims 76-79, 90-93, 95-99, 103 and 105-111 remain rejected under 35 U.S.C. 103(a) as being anticipated by Jaynes et al (U.S. Patent 5,811,654) in view of Applicants' Admission. This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

No claims are allowed.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

15 Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.  
March 6, 2003

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*Elizabeth F. McElwain*  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600